

TALKING POINTS
SCIENCE ADVISORY BOARD'S REVIEW OF EPA'S
DRAFT RISK ASSESSMENT AND POLICY GUIDE

The panel's conclusions on the risk assessment can be described only as irrational. The members acknowledged that the data presented in the report do not support the conclusions made and they agreed with virtually every criticism of the documents made.

The SAB's recommendations now go back to the EPA -- and EPA will make revisions. The panel has requested an additional review of the risk assessment once revisions are complete. Given that the SAB has asked for a rewrite of virtually everything in the draft report except the conclusions, a re-review is essential.

In revising its risk assessment, EPA has said -- in recent Congressional hearings -- it will consider several studies published since the initial draft was completed.

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- o The most recent ETS - lung cancer study to appear in the scientific literature -- a large case-control study of a population of Chinese women -- found no association between spousal smoking and lung cancer. In fact, the study reported a statistically significant inverse relationship between spousal smoking and lung cancer risk. Despite the fact that one of the members of the SAB committee which reviewed the ETS risk assessment was a co-author of the study, this research was never mentioned during the SAB's deliberations, nor was it provided for inclusion in the risk assessment's calculations.
- o When this and three other studies omitted by EPA are included in the Agency's meta analysis (the statistical procedure for combining the results of a number of studies to derive a single estimate of relative risk) -- using EPA's own method -- the results are not statistically significant. In other words, when the new studies are added, ETS exposure is not statistically associated with risk of lung cancer in nonsmokers.

The draft document is the first risk assessment ever conducted by EPA that is based entirely on epidemiologic evidence. The validity of the conclusions therefore depends entirely on the validity -- or lack thereof -- of this data. A review of the studies relied upon by the EPA reveals the following:

- o 24 studies are listed in the ETS report -- only five have reported a statistically significant association.
- o Of nine existing U.S. studies, none has reported a statistically significant association between spousal smoking and lung cancer in nonsmokers.

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During the review process, the SAB acknowledged that the existing report, based on flawed epidemiologic studies, did not adequately "make the case" that ETS is a cause of lung cancer in adults or respiratory effects in children.

Based on its "belief" that the conclusions are true however, the SAB recommended a number of revisions that it believes will bolster the case, including the instruction to analyze the data on mainstream smoking to prove that ETS must be harmful.

- o Such a suggestion disregards the fact that ETS and mainstream smoke are two different substances and different exposures.
- o This approach also disregards the report of the National Academy of Sciences which recognized qualitative and quantitative differences between ETS and mainstream smoke and raised doubts about the appropriateness of extrapolating to ETS from data on mainstream smoking.

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BACKGROUND

The Environmental Protection Agency (EPA) is developing three draft documents that address the alleged health effects of environmental tobacco smoke (ETS):

- 1) A "risk assessment" of ETS, released in draft form in June, 1990, which concludes that ETS causes 3700 nonsmoker lung cancer deaths per year.
- 2) A workplace policy guide which outlines various options for mitigation of ETS exposure and claims that only smoking bans or separate sections with separate ventilation will sufficiently reduce nonsmoker exposure.
- 3) A compendium of technical information on ETS, with eleven chapters drafted by various EPA contractors. Despite the fact that this document is designed to provide the technical basis for the workplace policy guide, it has not been finalized by the agency and so has not been made available for public comment.

The EPA's Science Advisory Board met December 4 and 5, 1990 to consider the draft ETS risk assessment and policy guide. At the conclusion of the hearing, the committee chairman announced at a news conference that the group had reached a consensus that ETS is a cause of lung cancer in nonsmokers. On the issue of respiratory effects in children, the chairman and several other panel members recommended that the EPA strengthen its conclusion regarding respiratory effects in children to note a causal relationship.

On the policy guide, the panel approved most of the health effects discussions in the draft but noted that EPA should not make claims about health effects that are not addressed in the risk assessment.

Despite its agreement with the risk assessment's conclusions, the panel overall was quite critical of the report and recommended a number of revisions that will require significant additional work. Criticisms of the report included:

1. The panel did not agree that EPA had established convincingly the conclusions that ETS is a cause of lung cancer in adults and respiratory disease in children. Instead, EPA was instructed to revise the report to "make that case."
2. The panel agreed with most of the criticisms leveled against the risk assessment by expert scientists who presented their opinions of the report during the hearing. Specifically, the panel agreed that numerous possible sources of bias and confounding had not been dealt with sufficiently in the report and that the individual studies should be reviewed more carefully in the final report.

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3. The panel suggested that, in addition to reviewing the epidemiologic studies of ETS and lung cancer, the report should take into account data on the reported health effects of active smoking to support the conclusions on ETS even though a report from the National Academy of Sciences has recognized qualitative and quantitative differences between ETS and mainstream smoke and raised doubts about the appropriateness of extrapolating to ETS from data on mainstream smoking.

Discussions of the SAB review should that:

1. One member of the panel expressed clear dissent from the majority's conclusions, describing as "rash" the recommendation that ETS be designated a Group A carcinogen. Several others raised objections to key elements of the risk assessment. This difference of opinion demonstrates that the issue of whether ETS causes disease is controversial within the scientific community and not settled as anti-smokers like to claim.
2. Despite press reports to the contrary, the SAB panel members chosen to review the documents were not biased in favor of the tobacco industry.
 - a) Anti-smoking activists claimed that six of the panel members were biased in favor of the tobacco industry, based on their association with the Center for Indoor Air Research. (The Center for Indoor Air Research was established in 1988 to fund independent research projects on indoor air quality issues. The Center receives funding from tobacco companies and others.) In fact:

Not one of these scientists has ever demonstrated the slightest bias in the industry's favor.

Indeed, several of the scientists who have been singled out by the media have written articles or made statements that are flatly inconsistent with the industry's position on ETS.

None of the six scientists who have been mentioned in recent media stories was proposed by the industry to participate in the review.

In fact, four of the six panel members singled out by the media are standing members of the EPA's indoor air advisory committee -- and were therefore automatically members of the current panel.

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- b) At the request of the Agency, The Tobacco Institute proposed a number of eminent scientists with no stake in the outcome of the review for inclusion on the panel. None of the scientists suggested by The Tobacco Institute was contacted to participate.
- c) In contrast, of six candidates proposed by anti-smoking activists, three are on the panel. This includes David Burns, an avowed anti-smoking activist who was temporarily removed from the panel based on the conclusion that he had demonstrated a clear bias against the tobacco industry. Despite this conclusion, announced by SAB staff, Dr. Burns was reappointed to the panel in response to complaints by anti-smoking groups.

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